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In the Supreme Court of the United States

OCTOBER TERM, 1946

UNITED STATES OF AMERICA, PETITIONER

v.

JORDAN JAMES SULLIVAN, TRADING AS SULLIVAN'S PHARMACY

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIFTH CIRCUIT

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CITATIONS

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The Acting Solicitor General, on behalf of the United States, prays that a writ of certiorari issue to review the judgment of the Circuit Court of Appeals for the Fifth Circuit, reversing the judgment of the District Court for the Middle District of Georgia convicting respondent for violating Section 301 (k) of the Federal Food, Drug, and Cosmetic Act.

OPINIONS BELOW

The opinion of the circuit court of appeals (R. 58–63) is not yet reported. The opinion of the district court (R. 11–27) is reported at 67 F. Supp. 192.

JURISDICTION

The judgment of the circuit court of appeals was entered May 12, 1947 (R. 63). The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925. See also Rules 37 (b) (2) and 45 (a), Federal Rules of Criminal Procedure.

QUESTIONS PRESENTED

1. Section 301 (k) of the Federal Food, Drug, and Cosmetic Act prohibits the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to," a drug, if such an act is done while "such article is held for sale after shipment in interstate commerce and results in such article being misbranded." The question is whether this provision extends to a retail druggist who misbrands a drug after it has reached his shelves.

2. If so, whether Section 301 (k) is a constitutional exercise of the commerce power.

STATUTE AND REGULATION INVOLVED

The Federal Food, Drug, and Cosmetic Act, June 25, 1938, c. 675, 52 Stat. 1040 (21 U. S. C. 301, *et seq.*), provides in pertinent part:

> SEC. 301. The following acts and the causing thereof are hereby prohibited:
>
> * * * * * *
>
> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that

is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise. [21 U. S. C. 331 (c).]

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded. [21 U. S. C. 331 (k).]

* * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine. [21 U. S. C. 333 (a).]

* * * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or

against unsafe dosage or methods of duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement. [21 U. S. C. 352 (f).]

Regulation 2.106 (b) promulgated by the Acting Administrator on April 10, 1941, 6 Fed. Reg. 1920, provides:

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of clause (1) of section 502 (f) of the Act if:

(1) Such shipment or delivery is made for use exclusively by or on the prescription of physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device;

(2) Adequate directions for so using such drug or device are available in scientific publications or otherwise;

(3) The label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ------", or "Caution: To be used only by a ------", the blank to be filled in by the word "Physician", "Dentist", or "Veterinarian", or any combination of two or all of such words, as the case may be;

(4) No representation appears in the labeling of such drug or device with respect to the conditions for which it is to be used; and

(5) In the case of a drug which is not designated solely by a name recognized in an official compendium and which is fabricated from two or more ingredients, its label also bears the quantity or proportion of each active ingredient.

Such exemption shall remain valid until all of such shipment or delivery is used by physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device, or is dispensed upon, and under labels bearing the directions for use specified in, prescriptions of such physicians, dentists, or veterinarians. But if such shipment or delivery, or any part thereof, is otherwise disposed of as a drug or device, such exemption shall thereupon expire. The causing by any person of such an exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable unless, prior to such disposition, such drug or device is relabeled to comply with clause (1) of section 502 (f) of the Act.

* * * * *

STATEMENT

On December 31, 1945, an information in two counts (R. 2–8) was filed in the United States District Court for the Middle District of Georgia

charging respondent with violations of the Federal Food, Drug, and Cosmetic Act. Each count alleged that a bottle containing sulfathiazole tablets was shipped in interstate commerce from North Chicago, Illinois, to Atlanta, Georgia; that the bottle was then sold to respondent with the same label as when shipped in interstate commerce; that on a specified occasion, while respondent held the drug for sale in his drug store, he removed 12 tablets from the bottle, repacked them in a box bearing on the label only the name of the drug, and sold them; that the drug, as so repacked and sold, did not bear adequate directions for use as required by Section 502 (f) (1) of the Act and did not bear certain warnings required by Section 502 (f) (2) of the Act; and that the drug was thus misbranded, in violation of Section 301 (k) of the Act.[1]

On February 8, 1946, respondent filed a motion to dismiss the information (R. 10), in which he urged that no offense was charged; that his acts were not in interstate commerce and were thus beyond the power of Congress to regulate; that properly construed, Sections 301 (k) and 502 (f) (1) and (2) apply only to misbranding in interstate commerce; and that if Section 301 (k) were construed to apply to respondent's acts, it is un-

[1] The first count charged the respondent with causing the doing of the prohibited act. The second count alleged that respondent performed the act.

constitutional and in violation of the Tenth Amendment. On June 19, 1946, the district court filed an opinion (R. 11–27) rejecting respondent's contentions.

Regulation 2.106 (b) of the Food and Drug Administration (*supra*, pp. 4–5) permits the shipment of various drugs in interstate commerce without appropriate instructions as to use if the drug is labeled with the prescription legend—"Caution: To be used only by or on the prescription of a physician"—and if various other specified conditions are satisfied. The regulation is designed to deal with those drugs for which adequate directions for lay use cannot be devised. As we show below, it was pursuant to this regulation that the drug in this case was shipped in interstate commerce.

Respondent waived a jury trial (R. 28). The undisputed evidence at the trial showed that during the period between November 25, 1943, and March 15, 1944, Abbott Laboratories shipped to itself at Atlanta, Georgia, bottles containing 1,000 tablets of sulfathiazole and bearing a warning that the tablets were to be "used only by or on the prescription of a physician." Respondent purchased one of these bottles in Atlanta, and it was shipped to him at Columbus, Georgia, where he operated a retail drug store. On December 13, 1944, an inspector of the Food and Drug Administration purchased, without a doctor's pre-

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scription, 12 sulfathiazole tablets from respondent's drug store. On the following day another inspector made a similar purchase. In both instances, immediately prior to the sale, the tablets which were sold were removed from the container in which they were shipped and which bore the warning against their use without a physician's prescription;[2] they were placed in small containers on which only the name of the drug—sulfathiazole—appeared (R. 29–31, 32–34, 35–37, 38).

Respondent was convicted on both counts (R. 49). The court suspended imposition of sentence

[2] The label on the bottle which was shipped in interstate commerce and from which the 12 tablets were removed in each instance read as follows (see R. 3, 29):

"1000 Tablets (Bisected)
"Sulfathiazole
"(2-sulfanilamidothiazole)
"0.5 Gm. (7.7 grs.)
"Abbott
"List No. 3430

"Caution—To be used only by or on the prescription of a physician.

"Warning: In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request.

"F5 Serial No. 311T237.

"Abbott Laboratories,
"North Chicago, Ill., U. S. A."

and placed respondent on probation for two years on condition that he pay a fine of $200 (R. 50–51). Upon appeal to the Circuit Court of Appeals for the Fifth Circuit, the judgment was reversed on the ground that respondent's acts did not constitute a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act (R. 58–63). It was the view of the court that Section 301 (k) applies only to the act of the importer of the interstate shipment and that it does not apply to a retailer who secures the drug intrastate from the importer.

SPECIFICATION OF ERRORS TO BE URGED

The circuit court of appeals erred:

1. In reversing the judgment of the district court.

2. In holding that the act of a retailer in removing a drug, which he held for sale after shipment in interstate commerce, from its properly labeled interstate container and placing it in another container without appropriate labeling is not a violation of Section 301 (k) of the Federal Food, Drug, and Cosmetic Act.

REASONS FOR GRANTING THE WRIT

This case presents for the first time in this Court the question of the proper construction to be given Section 301 (k) of the Federal Food, Drug, and Cosmetic Act. As we shall show, the construction adopted by the Fifth Circuit un-

necessarily limits the plain words of the provision to the extent of rendering it largely meaningless, and it seriously impairs the functioning of the Food and Drug Administration in its efforts to protect the consuming public against the ill effects of misbranding.

1. Section 301 (k) is a statutory embodiment of this Court's recognition in *McDermott* v. *Wisconsin*, 228 U. S. 115, that even after an article which has been shipped in interstate commerce reaches the retailer's shelves, the label under which it traveled in the stream of commerce must be protected. In the *McDermott* case, the reason for protecting the label was to make it possible to ascertain whether the article had lawfully been shipped in interstate commerce. Section 301 (k) is not limited to this purpose of protecting the label. As the House Committee Report (No. 2139, 75th Cong., 3d sess., p. 3) explains:

> In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph [301] (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.

The words of the statute plainly reflect this purpose. For in broad terms they proscribe the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect

to" a drug if such an act is done while "such article is held for sale after shipment in interstate commerce and results in such article being misbranded." So far as constitutionally permissible, this provision prohibits the doing of anything to a label on a drug or to the drug itself which results in the drug being misbranded within the meaning of the Act.

If the drug in question had been shipped in interstate commerce with a label containing merely the word "sulfathiazole," it would have been misbranded. For such a label does not contain adequate directions for use and the necessary warnings, as required by Section 502 (f) (1) and (2) of the Act. Here, after the drug reached the retailer's shelf and while he was holding it for sale, he did an act which resulted in the drug being misbranded within the meaning of these provisions. While he did not tamper with the interstate label itself, he did, by removing part of the contents from the properly labeled container and placing them in an improperly labeled container, accomplish the same result of misbranding in such a way that the drug as relabeled could not lawfully have been shipped in interstate commerce. This was, we submit, the doing of "any other act with respect to" a drug which "results in such article being misbranded." The court below conceded that the words of Section 301 (k), "in their broadest possible sense," reach the act done here (R. 60).

The court held, however, that the portion of Section 301 (k) which proscribes acts of the character involved here must be limited to "the first sale by the importer after interstate shipment" (R. 60).[3] On this theory, if the retailer himself imports the goods from outside the state, as in the *McDermott* case, he would be subject to the Act. But if the interstate importer is a distributor who sells intrastate to a retailer, the former may not do anything with the article which results in misbranding, but the retailer may do so with impunity. There is nothing in the language of Section 301 (k), which extends to articles "held for sale after shipment in interstate commerce," which justifies such a distinction between retailers purchasing interstate goods from interstate or intrastate wholesalers. The consequence of the adoption of any such distinction would be to permit any retailer to circumvent the statute by purchasing from a wholesaler within the state instead of directly from the producer or from an extrastate wholesaler.

It is plain from the Fifth Circuit's opinion that the court gave Section 301 (k) a restrictive construction, notwithstanding the plain words of the

[3] The court apparently thought that any mutilation, alteration, destruction, obliteration, or removal of the whole or any part of the interstate label itself by any dealer in the state of destination, whether on the first or subsequent transfers within the state, was within the valid scope of Section 301 (k) (see R. 60–61).

statute and the evident Congressional purpose to the contrary, because it had doubts that the provision could constitutionally extend beyond the act of the importer to that of the ultimate retailer. We are unable to agree with the court below that the Constitution requires this result. If it does not, the statute should be given its intended meaning.

This Court has repeatedly sanctioned federal regulation of intrastate activities where such regulation is appropriate to the effective and successful regulation of commerce. See *United States* v. *Wrightwood Dairy Co.*, 315 U. S. 110, 119; *Wickard* v. *Filburn*, 317 U. S. 111, 124; *United States* v. *Darby*, 312 U. S. 100, 118–122. In the *McDermott* case, the label under which a food moved in interstate commerce was protected, even against state action, after the product had reached the retailer's shelves awaiting sale to ultimate consumers. The situation is no different here. The drug in question had moved in interstate commerce under the sanction of the federal law because it was not misbranded. When it reached the retailer's shelf, acts were done which constituted an obvious misbranding of the drug. The purpose of the Food, Drug, and Cosmetic Act is to prevent goods shipped in interstate commerce from harming consumers. As this Court said in *United States* v. *Dotterweich*, 320 U. S. 277, 280, "The purposes of this

legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection." If, after the federal government has permitted a drug to be shipped in interstate commerce, the local seller may destroy the protective label which the federal government required or otherwise misbrand the product, the purpose of the Act will be defeated. The reason for requiring proper labels will be frustrated and the ultimate consumer will be deprived of the protections the Act was designed to safeguard. See *McDermott* v. *Wisconsin*, 228 U. S. 115, 130–131. The decision below allows the local dispenser the advantages of interstate distribution under unquestionably valid conditions prescribed by Congress in order to obtain the products he deals in, but permits him to nullify the very conditions under which the interstate shipment was sanctioned by misbranding the product before it reaches the ultimate consumer, for whose benefit the Act exists. The obvious intendment of Section 301 (k) was to prevent such acts of misbranding as an appropriate means fully to effectuate the purpose of the Act to protect the consuming public by closing the channels of interstate commerce to deleterious and misbranded foods and drugs.

We submit that the commerce power does permit the federal government to insist that when a

drug is permitted to move in commerce on condition that it is not misbranded, the condition shall not be subverted thereafter by misbranding the product before it reaches the ultimate consumer,

2. We are advised by the Administrator of the Act that the views expressed here have been adhered to consistently in the administration of the Act. Regulations relating to the movement in interstate commerce of numerous foods and drugs have been framed on the assumption that Section 301 (k) forbids a retailer from misbranding a product which has moved in interstate commerce. An extensive enforcement program has been carried out to insure compliance with Section 301 (k). The adverse effect which the decision below, if it is not reversed, will have on the enforcement of the Federal Food, Drug, and Cosmetic Act and on the protection to consumers contemplated by it is illustrated by the following examples which have been suggested by the Administrator.

a. Considerable success has been had in the enforcement of Section 502 (a) of the Act so as to eliminate from drugs and devices false and misleading claims of their efficacy in the treatment of ailments, such as cancer, tuberculosis and diabetes. The salutary effect of such enforcement may be completely dissipated if the first intrastate purchaser can, with impunity, relabel the articles

with the same false and exorbitant claims which the act has outlawed.

b. Section 502 (d) requires that the statement, "Warning—May be habit forming," appear on certain drugs; Section 502 (f) (1) and (2) require adequate directions for use and warnings against misuse. If a local dealer may remove these labels with impunity, the statutory provisions are requirements which exist only to be frustrated.

c. There are some drugs, as in this case, for which adequate directions for lay use cannot be devised. These drugs should be dispensed only on prescriptions by physicians. Regulations promulgated under Section 502 (f) (1) have exempted such drugs from bearing adequate directions for use, and have required such drugs to bear the "prescription legend" (*supra*, pp. 4–5, 7). It was contemplated that such drugs would be sold only on prescription, and the regulations were based on the assumption that Section 301 (k) could be invoked to protect the label on the drugs while they are held for sale after shipment in interstate commerce. The decision below removes this protection.

d. The regulations which have been promulgated under the Act with respect to insulin, penicillin, and streptomycin have been based on the assumption that Section 301 (k) reaches the act of misbranding while these drugs are held for

sale. In a letter to the Speaker of the House of Representatives, dated January 22, 1947, recommending the passage of a bill providing for the certification of drugs composed wholly or partly of streptomycin, the Federal Security Administrator advised the Congress, *inter alia*, of the Administrator's reliance on Section 301 (k). See H. Rep. No. 75, 80th Cong., 1st sess.; see also a similar letter sent to the Chairman, Senate Committee on Interstate and Foreign Commerce, on February 25, 1947, S. Rep. No. 45, 80th Cong., 1st sess.

e. With respect to food, the evils are also great. In recent years, the Administrator of the Act has initiated actions under Section 301 (k) for false rebranding of horse meat as beef; of cottonseed and soybean oils as olive oil; of imitation black pepper as pure pepper; of imitation orange beverage as pure orange juice; of Japanese crab meat as Russian crab meat; of domestic cheese as imported cheese; and of shrimp canned without federal inspection as shrimp canned under federal inspection. Under the decision below, any of these acts by one who is not the importer would be beyond the reach of federal control.

CONCLUSION

The question presented is one of great importance in the administration of the Federal Food, Drug, and Cosmetic Act. The decision

below limits the plain words of Section 301 (k) beyond their fair meaning and the evident congressional purpose, because of the court's doubts as to the constitutionality of a broader construction. Only this Court can finally resolve the constitutional question. We therefore respectfully submit that this petition for a writ of certiorari should be granted.

GEORGE T. WASHINGTON,
Acting Solicitor General.

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